DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 11, 2014

OptiMedica® Corp.
% Mr. Steve Jwanouskos
Associate Director, Regulatory Affairs
1310 Moffett Park Drive
Sunnyvale, CA 94089

Re: K141079
Trade/Device Name: Catalys® Precision Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: August 1, 2014
Received: August 4, 2014

Dear Mr. Jwanouskos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141079

Device Name
Catalys Precision Laser System

Indications for Use *(Describe)*

The OptiMedica® Catalys® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K141079

510(k) Summary

The following 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92:

5.1.1. Applicant

OptiMedica® Corporation[1]
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Sunnyvale, CA 94089
Phone: 408.850.8600
Fax: 408.583.4380

5.1.2. Contact Person

Steve Jwanouskos
Associate Director, Regulatory Affairs
OptiMedica® Corporation
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Sunnyvale, CA 94089
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5.1.3. Date Prepared

April 22, 2014

5.1.4. Classification

Class II
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Classification Product Code: OOE
Classification Product Code Name: Ophthalmic Femtosecond Laser

5.1.5. Trade Name

OptiMedica® Catalys® Precision Laser System

5.1.6. Predicate Devices

- OptiMedica Catalys™ Precision Laser System; K121091

5.1.7. Intended Use

The OptiMedica® Catalys® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

[1] *OptiMedica® Corporation was acquired by Abbott Medical Optics in August 2013, and currently retains its original legal name.*

5.1.8. Device Description

OptiMedica's Catalys® Precision Laser System ("Catalys® System" or "System") is a Class II ophthalmic surgical laser system as defined by regulation number 21 CFR 886.4390. The Catalys® System is indicated for use in cataract surgery to create a precise anterior capsulotomy and/or to effect phacofragmentation, thus facilitating efficient lens removal. The System also creates single-plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure. The System employs femtosecond ("FS") laser technology with integrated Optical Coherence Tomography ("OCT"), all of which are controlled and monitored by dedicated electronics. The System utilizes a common optical path for the OCT and femtosecond treatment laser (including the three-dimensional scanner and Liquid Optics™ [patient] Interface). As such, the beams are intrinsically co-registered and provide for precise overlap between imaging and treatment beams. In addition to the laser classifications per 21 CFR 1040.10 and 1040.11, the Catalys® Precision Laser System complies with the requirements for Class I lasers per ANSI Z136.1-2007 as well as to ISO 15004-2:2007.

5.1.9. Substantial Equivalence

The OptiMedica® Catalys® Precision Laser System is substantially equivalent to the predicate device in terms of indications for use, technological characteristics and performance specifications. The mechanism of laser cutting is the same for all three systems in that the ultra-short laser pulses create a highly localized plasma and subsequent cavitation event that when controlled by a computerized scanning system direct the laser beam through a three-dimensional pattern to produce a precise capsulotomy, fragment the crystalline lens and create arc cuts/incisions in the cornea.

5.1.10. Summary of Bench and Animal Performance Testing

Bench testing of the Catalys™ System was conducted to demonstrate the System's ability to deliver a variety of laser patterns intended for corneal incisions with corresponding accuracy and precision. In this test, the System's entire suite of corneal incision patterns was bracketed to test the full spectrum of physician-selectable pattern variations. Multiple samples for a given test pattern were created in a test substrate that was subsequently cross-sectioned and measured using a NIST-traceable reticule, under magnified digital image analysis. All measured values met the test protocol acceptance criteria of ±75µm relative to the intended cut dimensions. The spectrum of pattern testing validated the system capability to cut a variety of single plane and multi-plane arc cuts/incisions patterns within specified limits for accuracy and precision.

Animal testing was performed to demonstrate corneal safety. In this test, laser created corneal incisions and standard manual surgical incisions histology was compared. The laser parameters selected for this performance testing represent a worst case type evaluation using the minimum horizontal and vertical spot spacing coupled with maximum pulse energy. Each and all laser created corneal incisions met the histological acceptance criteria when compared to manual surgical incisions histology.

Cadaver eye testing was also conducted to demonstrate qualitatively the intended laser incisions can effectively cut a verity of tissue types. In this test, laser parameters, such as horizontal and vertical spot spacing, and laser pulse energy were bracketed to assess the full capability of the system. Each and all laser created corneal incisions met the qualitative acceptance criteria.